OPINION

French law concerning medically-assisted reproduction

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France has had a law concerning respect of the human body, donation and use of parts and products of the human body, MAP and prenatal diagnosis since 29th July 1994. The Decrees were officially published on 7th May 1995. We believe that colleagues in other countries would find it interesting to read about the following main provisions. We set out first details of medically-assisted reproduction (AR) and then antenatal diagnosis (AND).

Medically-assisted reproduction

For clarity we shall first describe general points concerning the definition and objectives of AR in French law and then we shall deal with the texts concerning the problems created for the couple undergoing MAP and techniques involved in gamete or embryo donation. In the last part we shall discuss the texts concerning the approval and supervision of the activities of infertility clinics.

General

Definition
AR covers clinical and biological practices for in-vitro fertilization (IVF), transfer of embryos and artificial insemination as well as any techniques with similar results using AR outside the natural process (Article L-152-1).

The scope of application of the law is thus very wide, covering insemination with the husband's semen (AM) to intracytoplasmic sperm injection (ICSI), including IVF, with or without donor semen, and artificial insemination with donor semen (AID).

Aims
AR is intended to 'respond to the wish of a couple for parenthood' and 'It is intended to remedy a state of infertility the pathological nature of which has been medically diagnosed' (Article L-152-2).

It is thus clear that the law is intended for use in a medical context and excludes all social demands (single mothers and homosexual couples whose infertility can be medically diagnosed but is not pathological).

It can also be used in order to avoid transmission of serious disease (Article L-152-2) which includes acceptance of gamete donation (spermatozoa or oocytes) or receiving embryos in cases of genetic disease or human immunodeficiency virus (HIV) seropositivity of the male partner.

Conditions
'The man and woman of the couple must be alive, of reproductive age, married or able to prove 2 years' living together and give consent prior to transfer of embryos or insemination' (Article L-152-2).

The legislation repeats here that the couple should consist of a man and a woman (thus clearly excluding homosexual couples), they must be alive, thus excluding post-mortem insemination and transfer of fertilized eggs after the death of one of the parents who initiated the process [Cases: Parpaló, Gallon, Orhan (Rennes) and Pires (Toulouse)]. This also excludes IVF by implanting oocytes after natural menopause, as performed in Italy. Finally, couples must give written consent, as we shall see later.

The length of co-habitation will be evaluated by medical teams. Medical teams may request an investigation by the social service department (Article L-152-10). In the interests of the child, a period of at least 1 month, between the counselling and the decision of choosing AR, can be imposed on the requesting couple by the multidisciplinary medical team (Article L-152-10C). It seems to us that these problems are more theoretical than real since the mean period of infertility for IVF in France is 5.6 years and the waiting time for donor insemination (DI) in CECOS is >1 year.

Consent form
The couple must receive precise counselling from a multidisciplinary team on the techniques (with description) and information on adoption. Practitioners must provide a guidance document and there must be 1 month between giving the information and the decision (Article L-152-10). Confirmation of the request must be given by signing a consent form (Article L-152-10C).

The legislation thus expects multidisciplinary information from a team (gynaecologist, biologist, psychologist, etc.) in an infertility clinic, which is new in medical practice where, to date, contact with the patient has been counselled by only one physician. It is also expected that information on alternatives and adoption be available to avoid pressure of the medical team. A 'guidance document' must be provided and timing respected. These are similar to the provisions of the Abortion Act (1975).

The couple and medically-assisted reproduction

We have just seen that the legislation is clearly for the treatment of infertility in a couple and it has provided arrangements
which are intended to ensure the stability of the couple. The intention is clear—to facilitate the birth of a child to a stable, well-informed couple and to avoid single women coming to request insemination with a man who has no plans for parenthood. In addition to the technical regulations concerning acceptance of clinics (which we shall deal with later), the law requires both health safeguards and arrangements for embryos.

**Health safeguards**

In terms of AR techniques for married couples (AIH, IVF, etc.), the law requires that initiating techniques are 'dependent on health safeguards defined by the health ministry'.

We believe that these regulations should be the same as those available to couples procreating naturally. There is no reason why IVF for married couples should require a more detailed medical check-up than another couple being treated for infertility or than pregnant women. It is therefore necessary to provide a screening medical examination including family history, general examination, serology for transmissible infectious diseases (rubella, toxoplasmosis, syphilis, hepatitis) which are compulsory for normal pregnancies.

HIV serology is not compulsory but must be proposed. Difficulties may arise if the couple refuse testing or if the results are positive. This poses a problem for the acceptance or refusal of a couple for AR where one partner is HIV-positive. There may be a conflict between the opinion of the medical team and the couple's request.

**The embryo**

'An embryo may only be conceived *in vitro* in the case of and according to the objectives of medically-assisted procreation. It must be conceived with gametes from at least one of the couple' (Article L-152-3). The clear intention of the legislation is to avoid setting up banks of embryos originating from donated oocytes and spermatozoa which thus belong to nobody. Nothing is said on the definition or the status of the embryo except that 'a human embryo cannot be conceived except for AR'. A human embryo may not be conceived or used for commercial or industrial purposes (Article L-152-7). It may not be conceived 'for purposes of study, research or experimentation' (Article L-152-8).

**Embryo freezing is permitted**

Indeed, 'both members of a couple may give a written consent that fertilization of a number of oocytes may be attempted, possibly making it necessary to conserve the embryos with the intention of meeting their desire for parenthood for a period of up to 5 years'. 'Both members of the couple will be consulted each year to establish whether they still desire parenthood' (Article L-152-3). They 'may give consent for the embryos to be received by another couple'.

When death occurs the surviving member of the couple should be consulted to know 'whether s/he gives consent for the embryos to be received by another couple' (Article L-152-4). (Decree No. 95–560 of 6 May 1995 determines the obligations of infertility clinic on the matter of conservation of embryos and we shall see this below.)

The law thus authorizes freezing and conservation of the so-called 'supernumerary' embryos. Each year the infertility clinic must consult each couple to establish whether they still desire parenthood.

Considerable difficulties can be anticipated in the application of these texts. What should be done if the couple does not reply to the infertility clinic questionnaire? What should be done if a couple who has had twins or triplets wish to prolong conservation for longer than 5 years? What should be done if the couple has separated and have different opinions?

When death of one partner occurs, it is difficult to imagine the surviving wife accepting the donation of her embryo(s) to another couple whereas she might want a transfer for herself.

As the National Ethics Committee pointed out, who is better placed than the survivor of a couple to determine the future of the embryo, the potential human being that s/he has had a part in producing?

**Ceasing conservation**

'Embryos existing at the date of the implementation of the present law, for which it has been established that they are no longer part of a request for parenthood and where it has not been stated that they should not be received by another couple and that they satisfy the regulations for health safeguards in force at the time of their transfer may be received by a couple meeting the conditions of Article L-142-5. If egg donation is impossible and if the period of their conservation is already at least 5 years, conservation must be terminated' (Article 9).

The legislation clearly favours donation of embryos to infertile couples rather than ceasing conservation. This is authorized only for embryos frozen before the law came into force. Ceasing conservation is not authorized for embryos frozen after publication of the law.

'After evaluation of its application, the present law will be subjected to further examination by Parliament within a maximum of 5 years from its publication' (Article 21). The fate of frozen embryos which have not been donated to other couples will be determined at that time.

**Medically-assisted reproduction with gamete or embryo donation**

These techniques raise four types of problem in the application of the law: (i) the specific measures regarding donation; (ii) health safeguards; (iii) indications; and (iv) filiation.

**Measures specific to donation**

Gamete donation is defined as 'the provision by a third party of spermatozoa or oocytes for purposes of medically assisted reproduction' (Article L-673-1).

**The recipient couple**

The consent of both members of the recipient couple (married or cohabiting) must be obtained by joint declaration before a judge (or his representative) of the Court of their choice or before a Solicitor (Article 311-20 and Decree No. 95–23 of 24th February 1995). The consent can be revoked, before any treatment, by either of the members of the couple (Article L-673-2).

Before obtaining consent, the Judge or the Solicitor must...
inform the requesting couple: 'Of the impossibility of estab-
lishing filiation links between the child and the donor or of
taking any action concerning the latter's responsibility (Article
311-19)'; 'Of the ban on bringing any action contesting filiation
of the child unless it is proved that the latter is not the result
of assisted reproduction or that consent was invalid'; 'Of cases
where consent is invalid'; 'Of the possibility of legally
declaring paternity to a man who, having consented to med-
cially-assisted fertilization, then did not recognize the result-
ing child' (Article L-311-20).

'He who, having consented to medically assisted fertiliza-
does not recognize the resulting child, is legally responsible
to the mother and child' (Article L-311-20).

Donor couples

'A donor must be in a couple which has had children'.

'Written consent of the donor and of the other member of
the couple must be obtained. This consent may be changed at
any time (Article 665-11)'.

'No payment, in any form, is granted to anyone who permits
removal of parts of his body or collection of its 'products'.
The only exception, where appropriate, is the reimbursement
of costs involved according to terms established by the State
Council' (Article 665-13). This article repeats Article 16-6
which states that 'no remuneration may be granted to someone
who allows experimentation on his body, removal of parts of
his body or the collection of products of the same'. More
generally, 'The human body, its elements and products may
not form part of rights to patrimony' (Article 16-1).

'The donor may not know the identity of the recipient, nor
the recipient that of the donor'. No information making
possible the identification of either the donor of an element or
product of his body or of the recipient may be divulged.
'Departure from this principle of anonymity is permitted only
in cases of therapeutic need' (Article 16-7 and L-665-14).

'Gametes from the same donor may not be used to deliber-
ately result in the birth of more than five children' (Article L-
673-4).

'Artificial insemination of donated fresh spermatozoa and
mixing of spermatozoa is forbidden' (Article L-673-3).

'It is forbidden to advertise concerning a donation or
products of the human body for the benefit of a specific person
or for the benefit of a clinic or specific organisation'. This ban
does not prevent informing the public concerning donation of
parts and products of the human body. Such information is
provided under the responsibility of the Minister of Health
(Article L-665-12).

'The benefit of gamete donation cannot in any way be
subject to designation by the recipient couple to someone who
voluntarily accepts making such a donation for an anonymous
third party couple' (Article L-673-7).

Health safeguards

'Removal of elements and collection of products from the
human body are subject to health safeguards defined by
Decrees of the State Council' (Article L-665-15).

Currently Decrees Nos. 92-174 of 25th February 1992
and 94-416 of 24th May 1994 stipulate that the physician
responsible for the collection or removal of human gametes
from a donation for the purpose of MAP is required to ensure
firstly, that the results of biological analyses performed on the
donor are negative for: (i) detection of infection with HIV1
and 2 and HTLV1 and 2; (ii) detection of biological markers
of hepatitis B and C; and (iii) serological screening of syphilis
detection of biological markers of cytomegalovirus. The
physician must also ensure that the microbiological examina-
tion of semen is normal. Placing spermatozoa in quarantine
for 6 months before use (having performed second HIV
serology) is not compulsory although CECOS applies this rule
themselves.

Indications for gamete donation

The law says that medically-assisted reproduction with third
party donation may only be performed as a final indication
when 'MAP within the couple cannot succeed' (Article 1-52-
6). It is certain that couples and doctors turn to donation only
as a last resort. However, it is difficult to accept being legally
obliged to impose ICSI for a couple who might refuse it
because of insufficient evaluation of these techniques.
Do couples not have the right to prefer an AR technique
which, although not perfect, is better known and evaluated
than a technique still under evaluation?

Acceptance of embryo by another couple

'In exceptional circumstances, both members of a couple may give
written consent that embryos may be accepted by another
couple'.

'When death occurs the surviving member of the couple
should be consulted to know whether s/he would consent to
embryos being accepted by another couple (Article L-152-4).

'In exceptional circumstances a couple for whom AR without
recourse to a third party donor cannot succeed may receive an
embryo' (Article L-152-5).

'Accepting an embryo is subject to a decision by legal
authorities who have previously received written consent of
the couple originating conception'.

The judge should ensure that the requesting couple fulfils
the conditions set out in Article L-152-2 and should instigate
full investigations to evaluate the conditions of acceptance that
the couple is able to offer to the unborn child from family,
educational and psychological points of view'.

'The couple accepting the embryo and the couple who gave
it may not know the other's identity. However, in the case
of therapeutic necessity, a physician may have access to unidentifiable medical information concerning the couple who
gave up the embryo'.

'No payment to the couple giving the embryo may be
permitted in any form'.

'Accepting the embryo is subject to health safeguards in
particular screening tests for infectious diseases'

The legislation refuses the term 'embryo donation' which
would reify the embryo because only things can be given. An
embryo is a potential human being and so is different from
oocytes and spermatozoa which can be donated. Embryo
acceptance by another couple is authorized if it is without
payment and anonymous. Although health safeguards in terms
of transmission of infectious diseases are taken into account,
nothing has been said about transmission of hereditary diseases.
Surrogate mothers

‘Any arrangement related to procreation or gestation on behalf of someone else is invalid’ (Article 16-7).

‘The intermediary between a person or a couple who wishes to have a child and a woman accepting to carry that child for the purpose of giving it to be sanctioned. When these acts have been committed regularly or for financial gain the penalties are doubled’ (Article 227-12).

Procreation for another person is therefore strictly forbidden whether it is simple insemination or pregnancy after transfer of embryos from a couple with normal gametes but in which the woman has no uterus (hysterectomy or congenital absence).

Research on embryos

The decrees on this subject are very restrictive.

‘All experimentation on the embryo is forbidden’ (Article L-152-8).

‘In exceptional circumstances the man and woman of the couple may accept that studies are carried out on their embryos’. The decision should be given in writing. These studies must have a medical outcome and may not damage the embryo. They may be carried out only after favourable opinion of the National Committee of Reproductive Medicine, Biology and Antenatal Diagnosis.

This makes all research practically impossible except experimentation on embryos to be implanted.

Licensing and control of infertility clinics

The law provides that AR techniques ‘take place in a medical centre with a multidisciplinary medical team’ (Article 152-10).

Licensing

‘With the exception of insemination, clinical activities of medically assisted fertilization may only be performed in medical centres’ (Article L-184-1).

‘Biological activities of medically-assisted fertilization may only be performed in hospital laboratories or private medical laboratories’ (Article 1184-1).

‘Collection and cryopreservation for gamete donation purposes may only be carried out in public or non-profit making clinics authorized for that purpose. No payment for the act may be received by the practitioner for performing these activities’ (Article 673-5).

‘Clinical and biological activities should be carried out under the responsibility of a practitioner appointed for that purpose in each public hospital laboratory or private laboratory authorized to perform them’ (Article L-152-9).

Licensing applies to one or several of the following activities:

Clinical activities

These include oocyte harvesting; surgical collection of spermatozoa from the epididymis or the testis; and embryo transfer in the uterus.

Biological activities

These include: collection and treatment of spermatozoa for medically-assisted procreation; treatment of oocytes; IVF without sperm injection; IVF with sperm injection; gamete cryopreservation; and embryo cryopreservation.

Licensing is granted for 5 years by the Minister of Health after notification from the National Committee of Reproductive Medicine, Biology and Antenatal Diagnosis (Article 184-1).

All accredited infertility clinics ‘are required to present an annual report of activities to the Minister of Health’ (Article L-673-1-3).

The form, intervals and contents of periodic evaluation of MAP medical centres will be defined by Order of the Minister of Health (Article R-183-1-3). The authorized infertility clinics must: (i) respect good practice guidelines; (ii) keep copies of medical documents, records of consent etc., from couples; (iii) record in the medical file, the medical indications, dates of puncture, the number of oocytes collected, date of transfer, number of embryos transferred, and all information related to the outcome of pregnancies and the state of health of neonates.

For biological acts, the laboratory must have a designated room for collection of spermatozoa, a room for IVF with or without microinjection and specific equipment for which they must be able to ensure decontamination and sterilization.

The room allocated for the conservation of gametes and embryos must be equipped with anti-theft protection. For the conservation of gametes and embryos the laboratory must record the identity of the gamete provider (or the identification no. if it is a donation), place and date of freezing, dates and methods of use, the indications and identities of recipient couples. In addition, if it is a donation the centre must keep anonymous files containing the results of compulsory health screening tests and the number of children born from the donation (Article R-673-5-8). AR practice is strictly supervised since licensing must be obtained (except for artificial insemination), conditions of training, multidisciplinary personnel (gynaecologist, echographist, psychiatrist, etc.) and technical conditions are required. An annual report must be provided and an evaluation made by an outside agency. It is the first time that such precise conditions have been required for medical practice in gynaecology and obstetrics.

The National Committee of Reproductive Medicine, Biology and Antenatal Diagnosis

This committee is composed of practitioners proposed by their representative organizations, people chosen for expertise in AR, in obstetrics, antenatal diagnosis, filiation law and representative of relevant administrative and professional bodies as well as a representative of family associations. It has the responsibility of: (i) giving advice on the requests for licensing or renewal from practitioners under whose responsibility clinical and biological AR acts are performed; (ii) giving advice on the requests for approval or renewal from infertility clinics; (iii) giving advice on decisions to withdraw licences; (iv) participating in the follow-up and evaluation of licensed hospitals and private clinics and laboratories. It reports annually on the evolution of reproductive medicine, biology and antenatal diagnosis to the Minister of Health.
Antenatal diagnosis

Definition

'Antenatal diagnosis (AND) intends to detect particularly serious pathology in the embryo or fetus in utero' (Article L-162-16). This Article complements Article 16-4 of Law No. 94-653 related to respect of the human body which stipulates that: 'No-one may damage the integrity of the human being. All eugenic practices aimed at organizing the selection of individuals is forbidden'.

Here again, the purpose of AND is medical and may not in any circumstances lead to eugenic practice such as selection of sex or of individuals having particular genetic characteristics. This exclude social demands such as sex choice of the fetus.

Function

AND procedures must be preceded by 'medical genetic counselling' (Article L-162-16) the aims of which are to: (i) evaluate the risk of the child being born with a particularly serious disease, in view of family history or medical evidence gathered during the pregnancy; (ii) inform the pregnant woman of the details of this disease, the means of detection, possible therapeutic measures and the possible results which might be obtained; (iii) inform the patient of the inherent risks of sampling, their constraints and possible consequences.

The consulting physician should provide a signed declaration certifying that he has given the patient the above information. This declaration should be given to the practitioner performing the samples (Decree No 95-559 of 6 May 1995).

Cytogenetic and biological analyses for the purpose of establishing antenatal diagnosis may only be carried out in authorized public or private hospitals or private laboratories.

After consultation with the National Committee of Reproductive Medicine, Biology and Antenatal Diagnosis, a licence is granted for 5 years. Multidisciplinary centres for antenatal diagnosis should be created in public and private hospitals or clinics. The nature of the timing and content of the evaluation of these centres will be established by Order of the Minister of Health.

Termination of pregnancy

If termination of pregnancy is 'envisaged because there is a strong possibility that the child will be born with a particularly serious disease which is recognized as incurable at the time of diagnosis, one of the two doctors who signs the acceptance of termination must be in practice in a licensed multidisciplinary centre for antenatal diagnosis’ (Article 13).

Preimplantation diagnosis

'Diagnosis performed on cells taken from the embryo in vitro is only permitted in the following exceptional conditions: (i) a physician practising in a multidisciplinary centre for antenatal diagnosis must certify that, in view of the family history, there is a strong probability that the couple will give birth to a child with a particularly severe genetic disease which is recognized as incurable at the time of diagnosis; (ii) the diagnosis can be made only when one or several anomalies have been previously and precisely identified in one of the parents, (iii) both members of the couple must give their consent in writing that the diagnosis should be carried out; (iv) the only reason for the diagnosis is to reveal the condition and seek means of prevention and treatment.

Diagnosis may only be performed in a hospital specifically licensed after consultation with the National Committee of Reproductive Medicine, Biology and Antenatal Diagnosis. Thus antenatal diagnosis is also regulated. Its purpose is exclusively medical. Multidisciplinary centres are to be created. It will be noted that only biological activities require authorization and that terminations of pregnancy require the agreement of a physician practising in a multidisciplinary centre for antenatal diagnosis, which was not previously the case. No gestation limit has been fixed for such terminations.

It will be necessary to await the publication of the Decrees on the functioning of the centres in order to see, in particular, the place of obstetricians/gynaecologists in these structures and whether it will be necessary to have a register of the indications for termination of pregnancy.

Conclusions

After a long period of reflection marked by numerous reports and fruitful debates, France now has a law concerning reproductive medicine and antenatal diagnosis. It gives couples, physicians and researchers a body of rules which attempt to reconcile the respect due to the human being, medical practice and necessary research. This passing from 'Ethics to Law' will necessitate drawing up of complementary Decrees of application. The law will be reviewed in 5 years, showing the wisdom of legislation which does not wish to fix in a definitive text techniques and practices which are in a state of evolution.

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